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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,432	12/06/2001	Shau-Chi Chi	39734-176754	8720
23639	7590	11/15/2005	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			FOLEY, SHANON A	
		ART UNIT	PAPER NUMBER	
			1648	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/004,432	CHI, SHAU-CHI	
Examiner	<b>Art Unit</b>		
Shanon Foley	1648		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 02 September 2005 and 12 September 2005.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1,3-5,7,8,10-12,14,16 and 18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1,3-5,7,8,10-12,14,16 and 18 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

### **DETAILED ACTION**

Upon consideration of the newly submitted claims and further consideration of the prior art, prosecution is hereby reopened. The examiner sincerely regrets any inconvenience applicant experiences.

The teachings of Vakharia et al. (US 6,274,147 B1) are not applicable to the instant claims because in view of applicant's arguments submitted September 12, 2005.

#### ***Priority***

For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications as well as the status of the prior application. For example, "now US Patent 6,436,702" should be inserted into the first sentence of the specification.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, 7, 8, 10-12, 14, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claims are drawn to a vaccine and a methods of immunizing with a vaccine comprising an inactivated virus that has been obtained from a cell line. It is unclear from the claims how an inactivated virus is obtained from a cell line as inactivated viruses are not infectious and do not replicate.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 11, 12, 14 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dorson et al. (Journal of Fish Diseases. 1978; 1: 309-320, cited previously), or in the alternative, Dixon et al. (Journal of Fish Diseases. 1983; 6: 399-409).

The claims are drawn to a vaccine and a method of immunizing fish by immersion with an inactivated IPN virus obtained from a cell culture.

Dorson et al. anticipate an IPNV obtained by a cell culture that has been inactivated by UV. Dorson et al. anticipate administering the inactivated IPNV to trout. See the abstract, "Experimental fish and infection trials" on page 310 and "Ultraviolet inactivation of viruses" on page 311.

Alternatively, Dixon et al. anticipate inactivating IPNV obtained from a cell culture in various ways for vaccine use and administering the inactivated vaccine to fish, see the Materials and Methods section, "*In vivo* tests..." on page 406 and "Immunogenicity tests" on pages 406-407.

Although neither Dorson et al. nor Dixon et al. mention the cell line recited in the claims, there is no distinguishing difference between the instantly claimed inactivated virus obtained by a particular cell line and the inactivated virus obtained by another cell line that is administered by

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Dorson et al. or Dixon et al. Therefore, it is maintained that the vaccine and method steps of administering the vaccine is anticipated by Dorson et al. or Dixon et al. since there is no distinguishing characteristic imparted from the instant cell culture to the inactivated virus.

Applicant disagrees that the instant composition is a product-by-process claim, but amends the claims to recite “obtained from” in lieu of “produced in”. However, “obtained from” is synonymous with the phrase “produced in” and does not impart any distinguishing characteristics on the virus from the cell line it is derived from.

Applicant further submits a 132 declaration, which describes the unexpected result of propagating IPNV in the deposited cell line derived from a fish that is known to be impervious to IPNV infection and obtaining twice the titer of the virus propagated in a traditional cell line.

Applicant’s declaration has been fully considered, but is found unpersuasive. The unexpected infectivity of IPNV in non-susceptible host cells and the unexpected quantity of virus yielded therefrom characterize unexpected properties of the deposited cell line, not the virus of the vaccine composition or the instant methods of administering the vaccine.

Claims 1, 3, 7, 8, 10 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arimoto et al. (Aquaculture. 1996; 143: 15-22).

The claims are drawn to a vaccine and a method of immunizing fish by immersion with an inactivated NNV virus obtained from a cell culture.

Arimoto et al. anticipate inactivating NNV by various methods obtained from a cell culture and administering the inactivated vaccine to fish, see the Materials and Methods and Discussion sections. Although Arimoto et al. do not mention the cell line recited in the claims,

there is no distinguishing difference between the instantly claimed inactivated virus obtained by a particular cell line and the inactivated virus obtained by the cell line of Arimoto et al. for reasons discussed above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley  
Primary Examiner  
Art Unit 1648